V. 510(K) SUMMARY

K103631

510(k) SUMMARY JUL 2 1 2011

BiancaMed Ltd's SleepMinder Breathing Frequency Indicator (BM07)

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: 7th December 2010

Name of Device

SleepMinder Breathing Frequency Indicator (model BM07)

Common or Usual Name

Breathing Frequency Monitor

Classification Name/ CFR Reference /Product Code

Class II, Breathing Frequency Monitor, 21.CFR.868.2375 , Product code BZQ,

Predicate Devices

- Kai Sensors Kai R-Spot 100, Breathing Frequency Monitor, [K090273].
- Somnomedics SOMNOscreen Plus RC Easy, Ventilatory Effort Recorder, [K060708]

Intended Use / Indications for Use

The device is intended to be used for the spot measurement of respiration rate of an adult patient in a hospital and clinical setting. It is not a vital signs monitor or an apnea monitor.

The device is indicated for use as suitable for use on adult patients. It should not be used on patients that exhibit uncontrolled limb movement.

Product Description

The SleepMinder Breathing Frequency Indicator BM07 consists of

- A small sensor unit that can stand on a desk top or shelf. The sensor unit emits a very low power radio signal that is aimed at the patient. The sensor utilizes the reflected radio signal to measure the chest movement of the patient, and thus discern the respiration rate. The sensor has no part that is in contact with the patient.

- The sensor data is transmitted to a PC running a proprietary display program. The validated transmission method to the PC is a BlueTooth wireless link.

- The PC display program runs a proprietary algorithm to extract the respiration rate from the sensor movement data. The program displays

    - The respiration rate, and
    - Indicates whether there is a valid target, whether the target is moving too much for a breathing signal to be indentified or the signal is clear enough for a breathing rate to be calculated.

Technological Characteristics

The BM07 utilizes a 5.8GHz pulsed radar as its sensor technology. The Kai R-Spot utilizes a 2.4GHz continuous wave radar as it sensor technology. Both frequencies are in common use as radiolocation frequencies and are in license-free portions of the electromagnetic spectrum. The choice of centre frequency and pulsed or continuous wave are merely design and cost decisions: the lower frequency will require a larger antenna and so determine the device size and continuous wave radar is slightly cheaper than pulsed

radar to fabricate. There are no significant differences in the technological characteristics between the 2 devices.

Performance Data

Initially, the basic performance envelope of the BM07 was established in terms of the maximum effective range and the effects of different target aspects. These tests were carried out using the SOMNOscreen predicate device as a comparator device for the measurement of breathing rate. The SOMNOscreen has chest effort bands and so measures breathing rate by direct contact with the subject. However, it does not have a real-time readout, the data has to be processed after the end of the recording session and the breathing rate displayed in a graph against time. The BM07 recordings were similarly processed to facilitate comparison.

Validation testing was also carried out to confirm that the BM07 sensor continued to perform satisfactorily in the presence of typical potential RF interference emitters and also that the breathing rate calculation was stable across a number of individual examples of the device.

Finally, the overall performance of the system was tested on 24 volunteer subjects, of varying gender, height and BMI, against the SOMNOscreen Plus RC Easy [K060708] predicate device, which is classified as a ventilatory effort recorder, to replicate the bench tests of the Kai Spot.

In all instances, the SleepMinder Breathing Frequency Indicator BM07 functioned as intended and breathing rate observed was as expected.

Substantial Equivalence

The application cites 2 predicate devices:

- The Kai Sensors R-Spot 100 [K090273] is an RF-based non-contact breathing indicator. It is used to establish substantial equivalence in technology and intended use of the BM07 to a previously cleared device. Despite the company's best efforts, the Kai R-Spot 100 could not be procured for use in side-by-side performance testing, and so the performance testing was carried out against a SOMNOscreen Plus RC Easy.
- The SOMNOscreen Plus RC Easy [K060708] is a portable Ventilatory Effort recorder. The chest effort bands of the SOMNOscreen were used to collect the chest breathing effort and thus calculate the breathing

rate. The SOMNOscreen does not give a real time indication; the data is processed after the end of the recording session.

The SleepMinder Breathing Frequency Indicator BM07 is as safe and effective as the Kai Sensors Kai R-Spot 100. The SleepMinder Breathing Frequency Indicator BM07 has the same intended uses and similar indications, technological characteristics, and principles of operation as the Kai R-Spot 100. The minor technological differences between the SleepMinder Breathing Frequency Indicator BM07 and the Kai R-Spot 100 device raise no new issues of safety or effectiveness. Performance data collected against the SOMNOscreen predicate device demonstrate that the SleepMinder Breathing Frequency Indicator BM07 meets general market and scientific expectations of accuracy, as does the Kai R-Spot 100. Thus, the SleepMinder Breathing Frequency Indicator BM07 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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JUL 2 1 2011

Re: K103631
Trade/Device Name: SleepMinder Breathing Frequency Indicator (model BM07)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ
Dated: July 12, 2011
Received: July 15, 2011

Dear Mr. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/ CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/ Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known): K103631

Device Name: SleepMinder Breathing Frequency Indicator (model BM07)

Indications for Use:

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The device is suitable for use on adult patients. It should not be used on patients that exhibit uncontrolled limb movement.

Prescription Use X (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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